FEB - 6 2012

Section VII. 510(K) SUMMARY

Date Prepared
February 3, 2012

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Official Correspondent
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Establishment Number
3005129649

Device Name
Legally Marketed Trade Name: PATHWAY AVID
Common Name: Intervertebral Body Fusion Device
Device Classification: Class II
Regulation Number: 21 CFR 888.3080
Device Product Codes: MAX

Predicate Devices
PATHWAY AVID K090566

Description of Modified Device
The proposed modification subject device is to be provided to the users in one of two configurations: the predicate device containing PEEK Optima LT1with titanium hinges

and linkages (Ti-6Al-4V, ASTM F136) or the proposed PEEK Optima LT1 with MP35N (Co-Cr-Ni-Mo Alloy, ASTM F562).

Indications for Use

The PATHWAY AVID intervertebral body fusion device is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain with discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have Grade I Spondylolisthesis or retrolisthesis at involved levels. The patients may have had a previous non-fusion spinal surgery at the involved level(s).

The device is intended to be used with supplemental fixation systems that have been cleared for the lumbosacral spine (i.e. posterior pedicle screws and rod systems and anterior screw and rod systems). The device is intended to be used with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PATHWAY AVID device. The PATHWAY AVID Intervertebral body fusion device must be inserted from a transforaminal approach (TLIF).

Materials

This product is manufactured from PEEK (Polyetheretherketone) as per ASTM F2026 and contains either titanium (Ti-6Al-4V, ASTM F136) marker and linkages or MP35N (Co-Cr-Ni-Mo, ASTM F562) markers and linkages.

Performance Data

Tensile testing of the linkages was conducted comparing the predicate AVID Interbody Fusion Device (K090566) and the proposed modification. This mechanical data indicates that the linkage and hinge pins with the proposed modification show equivalence to the titanium linkages and hinge pins of the predicate. Previous mechanical testing conducted on the predicate (K090566) demonstrated that the failure modes were in the PEEK spacer, and not the linkage or hinge pins.

Corrosion testing was performed on the linkage system and the hinge pins in accordance with ASTM F 2129-08 "*Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices*". The data demonstrates that these devices display acceptable corrosion resistance in the ASTM F 2129 test. See complete test report in Section 2 of the Response to FDA Deficiency letter of 07 October 2011.

Substantial Equivalence Statement

Custom Spine believes that the proposed addition to the PATHWAY AVID family has the same indications for use, same technological characteristics, same design, and the same interbody material (PEEK) structure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 6 2012

Custom Spine, Inc.
% Mr. David Brumfield
Senior Vice President of Research
and Development, Quality and Regulatory
1140 Parsippany Boulevard, Suite 201
Parsippany, New Jersey 07054

Re: K111726
Trade/Device Name: PATHWAY AVID
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: January 27, 2012
Received: February 01, 2012

Dear Mr. Brumfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Peter D Rumm MD MPH
Rumm
CLIN DSP DIR

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section VII. Indications for Use

510(k) Number (if known): K111726
Device Name: PATHWAY AVID

The PATHWAY AVID Intervertebral body fusion device is intended for spinal fusion procedures at one or two contiguous levels (L2-Sl) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by the history and radiographic studies. DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. The patient may have had a previous non-fusion spinal surgery at the involved level(s).

The device is intended to be used with supplemental spinal fixation systems that have been cleared for lumbosacral spine (i.e. posterior pedicle screws and rods systems and anterior screw and rod systems). The device is intended to be used with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the PATHWAY AVID device. The PATHWAY AVID Intervertebral body fusion device must be inserted using a transforaminal approach.

Prescription Use ____X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111726